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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,937	09/30/2002	Geoffrey H. White	VAS-5511A	4752
30452	7590	03/17/2005	EXAMINER	
EDWARDS LIFESCIENCES CORPORATION ONE EDWARDS WAY LEGAL DEPARTMENT IRVINE, CA 92614			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,937

Applicant(s)

WHITE ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004 and 03 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Amendment filed 10/4/04 and Response to Notice of Non-Compliant Amendment filed 1/3/05 have been entered. The changes to the specification and drawings have been approved by the examiner, and the new abstract has been entered. Claims 1-20 have been canceled and new claims 21-40 have been added.

Priority

2. The certified copy of the Australian patent application PQ 3029 has been entered.

Claim Objections

3. Claims 23, 24, 35 and 36 are objected to because of the following informalities:

- a) In claim 23, line 2, it appears that "end" should be changed to --ends--.
- b) In claim 24, line 3, it appears that "end" should be changed to --ends--.
- c) In claim 35, line 2, it appears that "An" should be changed to --an--.
- d) In claim 36, line 3, it appears that the "a" before "at" should be deleted.
- e) In claim 36, line 8, it appears that "an artery" should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 21 and 35 require that the diameter of the tubular body be wider at the first end. Because "wider" is a relative term and the claim does not say what the first end is wider than, the claims are rendered indefinite.

6. Claims 25 and 27 are indefinite because "supplemental graft" on line 2 implies that there is already a graft. Claim 21 does not require a graft, so it is unclear how claims 25 and 27 can then require a "supplemental graft". It is also unclear what the supplemental graft is overlapping.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 21-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. (USPN 5,800,514 as cited in last office action) in view of Fogarty et al. (USPN 5,800,520 as cited in last office action).

Nunez et al. discloses an intraluminal device with all the elements of claim 1, but is silent to the first end being angled such that when viewed in a vertical cross-sectional plane, a portion

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of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end and of the first end having an opening that is non-circular. See Figure 7, column 3, lines 58-63 and column 9, lines 19-42 for an intraluminal device (500) comprising a tubular body (517) having a length, a first end (512), and at least one second end (514) wherein the tubular body is of a pre-determined non-linear shape. The diameter of the tubular body (517) at the first end (512) is wider than the rest of the tubular body, as interpreted by the examiner. Fogarty et al. teaches an intraluminal device wherein a first end is angled and provides a non-circular opening in order to reduce restenosis and avoid blocking branch vessels. See Figure 11, column 1, lines 10-14, column 3, lines 5-32 and column 9, lines 40-54. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Fogarty et al. to modify the intraluminal device of Nunez et al. by making the first end (512) of the tubular body (517) angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end in order to reduce restenosis and avoid blocking branch vessels. By making the first end angled, the opening created will by nature be non-circular.

Claims 22-24, see Figure 7 and column 9, lines 37-42 for a sigmoid curve along the length of the tubular body between the first and (512) at least one second end (514).

Claim 25, as best understood by the examiner, see Figure 7 and column 9, lines 19-42 for the entire tubular body (517) being a graft, thereby providing as the "supplemental graft" overlapping with the second end (514) of the tubular body (517).

The embodiment shown in Figure 7 of Nunez et al. is silent to the additional limitation of the tubular body (517) being bifurcated at the second end (514) and having two bifurcated limbs,

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as required by claim 26. Nunez et al. does, however, disclose that bifurcated grafts having an aortic woven portion and iliac leg sections are used in repairing aortic aneurysms. See column 6, lines 31-38, and Figure 15, for example. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the tubular body (517) of the embodiment shown in Figure 7 by bifurcating the second end (514) to have two bifurcated limbs in order for the intraluminal device (500) to be used in repairing aortic aneurysms, while still being able to closely match the shape of and internal diameter of the aorta. See column 1, lines 47-54.

Claim 27, as best understood by the examiner, see Figure 7 and column 9, lines 19-42 for the entire tubular body (517) being a graft. When the second end (514) is bifurcated, the entire tubular body (517) will still be a graft, thereby providing as the "supplemental graft" overlapping with the bifurcated limbs.

With respect to claims 28-30, "in an anterior-posterior plane" and "in a lateral plane" relate to the device when it is implanted into the body. Because the tubular body of the intraluminal device is matching the diameter and shape of the vessel it is being implanted into, it is inherent that the body will have curvature along its length in these planes.

Claim 31 is product-by-process claim, and according to MPEP § 2113, this claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. The tubular body is curved along the length between the first and at least one second end, and therefore meets the structural limitations of the claim. In addition, see column 2, lines 55-57 for it being old and well known in the art to use cutting in forming desired sized and shaped grafts.

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Claim 32, see Figure 9 for a first, unexpanded shape (grafts are flat-woven) and Figures 7 and 10 for a second, expanded, predetermined, non-linear shape.

Claims 33 and 34, see Figure 27 and column 16, lines 20-32 for a plurality of separate, spaced apart, longitudinally reinforcing wires. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the embodiment shown in Figure 7 by including a plurality of separate, spaced apart, longitudinally reinforcing wires in order to maintain the intraluminal device (500) within the lumen of the vessel to be repaired. See column 16, lines 14-17.

Nunez et al., as modified by Fogarty et al., discloses an intraluminal device delivery system with all the elements of claim 35. See the rejection to claim 21, *supra*, for the intraluminal device required limitations. See column 1, lines 32-37, column 2, lines 1-3 and column 3, lines 14-16 for Nunez et al. disclosing that it is old and well known in the art to use an intraluminal catheter in delivering a vascular graft. Because the catheter will bend according to the path of the vessel, the catheter is configured to be slightly curved along its length in at least one of an anterior-posterior plane or lateral plane when passed therein.

9. Claims 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khan et al. (USPN 5,928,258 as cited in last office action) in view of Milo et al. (USPN 5,816,923) and Nunez et al.

Khan et al. discloses a method for delivering and emplacing an intraluminal device with all the elements of claim 36, but is silent to the method step of determining the shape of at least a portion of a vessel of a patient by imaging and of the intraluminal device having a predetermined

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non-linear shape. See column 1, lines 21-45 and Figures 1-3 for disclosure of the state of the art including providing an intraluminal device (stent-graft 10), radially compressing an intraluminal device (stent-graft 10) and placing the device within a delivery device (sheath 22), introducing the delivery device (sheath 22) into the vessel of a patient when the device body (stent-graft 10) is in a radially compressed state, causing the device (stent-graft 10) to be moved through the delivery device (sheath 22) until the device (stent-graft 10) extends into the vessel from a proximal end of the delivery device (via plunger catheter), and allowing the device (stent-graft 10) to expand. The examiner contends that once delivery and deployment of the device is complete, it is inherent that the delivery device will be withdrawn. Milo et al. teaches determining the shape of a blood vessel using ultrasound in order to identify the nature, extent and location of the stenosis in the vessel and determine the method of treatment. See columns 1-2, lines 46-11. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Milo et al. to modify the method of Khan et al. by including the step of determining the shape of at least a portion of a vessel of a patient by ultrasound imaging (claim 38) in order to identify the nature, extent and location of the stenosis in the vessel and determine the method of treatment. Nunez et al. teaches an intraluminal device having a predetermined non-linear shape in order to closely match the shape of and internal diameter of the vessel into which it is implanted. See column 1, lines 47-54. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Nunez et al. to modify the intraluminal device (stent-graft 10) of Khan et al. by making it have a predetermined non-linear shape in order to closely match the shape of and internal diameter of the vessel. The intraluminal device will thereby be capable of abutting the

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surrounding wall of the vessel while the vessel deviates from its normal path (claim 37) and expand to take on its predetermined configuration (claim 40).

Claim 39, see Figures 1-3 for radially compressing the intraluminal device so that it takes on a linear shape.

Response to Arguments

10. Applicant's arguments with respect to claims 21-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

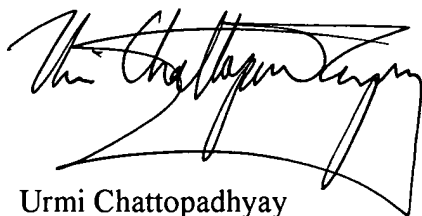
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

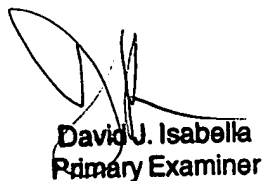
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David U. Isabella
Primary Examiner